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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,652	08/05/2002	Per-Ake Nygren	2039.003	4666

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Wiggin & Dana  
Intellectual Property Law Section  
Docket Coordinator  
One Century Tower  
New Haven, CT 06508-1832

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/030,652

Applicant(s)

NYGREN ET AL.

Examiner

Mark Navarro

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 14-16, 22, 23 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 17-21, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/29/02 + 5/19/03</u> | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, claims 1-13, 17-21, and 25 in the reply filed on November 8, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants have specifically pointed out that claim 24 does not belong with claims directed to DNA, and should be examined with Group I. Applicants comments that claim 24 does not belong with DNA are correct. Accordingly, claim 24 has been included with the claims of Group I.

Consequently, claims 1-26 are pending in the instant application, of which claims 14-16, 22-23 and 26 have been withdrawn from further consideration as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 20-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 20-21 are directed to proteins which have the same characteristics and utility as proteins found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-

statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Inoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated protein..."

### ***Claim Rejections - 35 USC § 112***

2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "functionally equivalent." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, which function is being measured (e.g., specificity, avidity, affinity, etc.)? Furthermore what level is then required to be considered functionally equivalent? Likewise at what point is the divergence sufficient to no longer be encompassed by functionally equivalent? Without a clear definition as to the metes and bounds of the term "functionally equivalent" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

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3. Claim 11, 13 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the use of the phrase "derived." Since it is unclear if the domain is undergoing any kind of chemical modification as implied by the recitation of "derived." Since it is unclear how the domains are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

4. Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "substantially the same." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, what level of identity or similar functions is required to be considered substantially the same? Likewise at what point is the divergence sufficient to no longer be encompassed by substantially the same? Without a clear definition as to the metes and bounds of the term "substantially the same" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-13, 17-19, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Nord et al.

The claims are directed to a self-assembled biomolecular structure comprising affinity modules, said affinity modules each having at least two affinity domains which may be the same or different, at least one affinity domain within each affinity module having specific and exclusive affinity for an affinity domain within another affinity module, said affinity modules capable of biospecific interaction to form an assembled structure.

Nord et al (Nature Biotechnology Vol. 15, August 1997, pp 772-777) disclose of small protein domains, capable of specific binding to different target proteins, called affibodies, fused to bacterial receptor domain Z, derived from Staphylococcal protein A. Nord et al further disclose that the Z-domain is able to spontaneously fold in the cytoplasm. Nord et al further disclose of affinity domains which have been selected from a molecular library. (See abstract and pages 775, 776).

It is noted that Nord et al do not disclose of the use of this structure for therapy (claim 25). However, this recitation is merely an intended use of the structure and therefore carries no patentable weight.

5. Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson et al.

The claims are directed to a protein molecule having the amino acid sequence of SEQ ID NO: 2/3 or variants thereof having substantially the same affinity for Staphylococcal protein A.

Nilsson et al (WO 95/19374) disclose of Z protein variant 22 and Z protein variant 17 which have 76.7 and 78.3 percent identity to SEQ ID NO: 2 and 3 of the instant invention, respectively. (See Figure 14).

Given that Nilsson et al disclose of proteins with high levels of homology, they are deemed to anticipate the claim language which recites "variants" of SEQ ID NO: 2 and 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
January 26, 2005